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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/171,607 | 11/04/1998 | WOLF-GEORG FORSSMANN | P63132USO | 8253 |

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EXAMINER

HADDAD, MAHER M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 08/12/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/171,607

Applicant(s)

FORSSMANN ET AL.

Examiner

Maher M. Haddad

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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RESPONSE TO APPLICANT'S AMENDMENT

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Maher Haddad, Art Unit 1644, Technology Center 1600.
2. Applicant's amendment, filed 6/24/03 (Paper No. 25), is acknowledged.
3. Claims 64-77 are pending and under examination.
4. Applicant's cancellation of Claims 43-62 have obviated the previous objections and rejections.
5. Claim 75 is objected to because of the following informalities: the use of the word "or" is improper. Appropriate correction is required.
6. The following is a quotation of the second paragraph of 35 U.S.C. 112.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 67-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - A) Claims 67-69 provide for a process for the preparation of the isolated peptide through prokaryotic or eukaryotic expression in claim 67, through isolation from human blood using chromatographic methods in claim 68, by solid-phase and liquid-phase synthesis and purification by chromatographical methods, but, since the claims do not set forth any steps involved in the process, it is unclear what process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.
8. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
9. Claims 64-77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

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The specification does not provide enablement for the peptide of SEQ ID NO:1, an amidated, acetylated, phosphorylated, or glycosylated derivative of the peptide of SEQ ID NO:1 in claim 64, the isolated peptide consisting of the amino acid sequence of SEQ ID NO:1 in claim 65, the isolated peptide consisting of the amidated, acetylated, phosphorylated, or glycosylated derivative of the isolated peptide in claim 66, a process for the preparation of the isolated peptide through prokaryotic or eukaryotic expression in claim 67, a process for the preparation of the isolated peptide through isolation from human blood using chromatographic methods in claim 68, a process for the preparation of the isolated peptide by solid-phase and liquid-phase synthesis and purification by chromatographical methods in claim 69; a medicament containing the isolated peptide according to claim 64 as the active ingredient in combination with excipients in claim 70, in a form for oral, parenteral, intravenous, intramuscular, intracutaneous, intrathecal or intranasal administration in claims 71-74, or in a form for local-topical or transpulmonary application in claims 75-76; or antibodies obtainable by immunizing animals with the isolated peptide of SEQ ID NO:2 or the recited derivative thereof or obtainable by using hybridoma technology in claim 77. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

At issue is whether or not the claimed composition would function as a medicament. In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the medicament as claimed, and absence of working examples providing evidence which is reasonably predictive that the claimed medicaments are effective for *in vivo* use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed medicament with a reasonable expectation of success.

The specification discloses the antiproliferative activity of SEQ ID NO:1 using *in vitro* proliferation assay in bovine capillary endothelial cells (see page 11, under example 2). The specification discloses that SEQ ID NO:1 to be useful as a medicament for the treatment diseases of the human organism, especially in connection with capillary proliferations, carcinoses, diseases involving the cardiovascular and nervous systems, diseases involving the intugement and the sense organs, especially the eyes (see page 5, 4th paragraph). The exemplification is drawn to inhibit cell proliferation of bovine endothelia cells *in vitro*. The specification fails to disclose how to use the claimed invention.

In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Since no animals were used as model system to treat capillary proliferations, carcinoses, diseases involving the cardiovascular and nervous systems, diseases involving the intugement and the sense organs, especially the eyes. It is not clear that reliance on the *in vitro* data of bovine endothelia cells inhibition of proliferation accurately reflects the relative mammal efficacy of the claimed therapeutic strategy. The specification does not adequately teach how to effectively treat capillary proliferations, carcinoses, diseases involving the cardiovascular and nervous systems, diseases involving the

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intugement and the sense organs, especially the eyes or reach any therapeutic endpoint in mammals by administering the medicament. The specification does not teach how to extrapolate data obtained from an in vitro assay studies to the development of effective in vivo mammalian therapeutic treatment, commensurate in scope with the claimed invention. Therefore, it is not clear that the skilled artisan could predict the efficacy of the medicament exemplified in the specification.

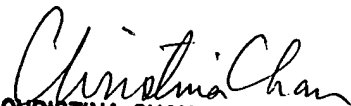
Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

9. No claim allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad, whose telephone number is (703) 306-3472. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
August 11, 2003


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600